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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/632,741      | 08/04/2000  | Brent Belding        | ACS-53498(21061)    | 2770             |

24201            7590            07/17/2003

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EXAMINER

CHATTOPADHYAY, URMI

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3738     | 10           |

3738

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

|                                       |                                       |  |
|---------------------------------------|---------------------------------------|--|
| <b>Application No.</b><br>09/632,741  | <b>Applicant(s)</b><br>BELDING ET AL. |  |
| <b>Examiner</b><br>Urmi Chattopadhyay | <b>Art Unit</b><br>3738               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 31 March 2003.
- 2a)  This action is FINAL.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-44 and 65-70 is/are pending in the application.  
4a) Of the above claim(s) 6,7,10,12,27,29 and 39 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-5,8,9,11,13-26,28,30-38,40-44 and 65-70 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 04 August 2000 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 3/31/03 has been entered as Paper No. 9. Claims 45-64 have been canceled and new claims 65-70 have been added. Claims 6, 7, 10, 12, 27, 29 and 39 remain withdrawn from consideration for being drawn to non-elected species. The claims pending are 1-44 and 65-70 and the claims being considered for further examination on the merits are 1-5, 8, 9, 11, 13-26, 28, 30-38, 40-44 and 65-70.
2. During an updated search new prior art was found readable on applicant's claimed invention. This office action is therefore non-final.

***Claim Objections***

- ✓ 3. Claim 70 is objected to because of the following informalities: on line 2, --which-- should be inserted after "perforations". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-26, 28, 30-35, 38 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ✓ 5. Claims 18, 20 and 23 are indefinite because they are inaccurate, according to the specification and drawings. In the embodiment shown in Figures 1-6, when inflation fluid is

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introduced into the means for expanding, the means for retaining is not configured to *detach* from the means for delivering. It remains attached to the means for delivering. In the embodiment shown in Figures 7A-7B, the means for retaining is configured to detach from the means for delivering when inflation fluid is introduced into the space between the means for retaining and means for delivering, not into the means for expanding. Applicant must clearly and accurately claim the invention of the elected embodiment.

In the amendment filed 8/30/02, applicant had corrected this indefiniteness by changing “detach from the means for delivering” to “rupture to allow the endoprosthesis to expand into a deployed position” in claim 18. Examiner will assume applicant mistakenly excluded this amendment to the newly amended claims 18, 20 and 23, and will interpret the claims, for examination purposes, as including the correct change made in the previous amendment.

6. Claim 35 recites the limitation "the endoprosthesis" in lines 9 and 10. There is insufficient antecedent basis for this limitation in the claim. It appears that “endoprosthesis” should be changed to --stent--.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 1-5, 8, 9, 13, 16-26, 30, 31, 33-36, 40, 41, 43, 44 and 65-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanson (USPN 6,432,130 B1).

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 3, 18, 20, 23, 35, 36 and 65. See abstract, Figures 1-5 and columns 2-3, lines 64-12 for a catheter assembly (10) for delivering an endoprosthesis within a body lumen including a catheter (14) having proximal and distal end portions, an expandable member (16) associated with the distal end portion of the catheter, an endoprosthesis (12) disposed on the expandable member, and a sheath (30) disposed on the catheter and over the endoprosthesis, wherein the sheath is configured to rupture into portions during expansion of the expandable member and retract towards first and second ends of the stent after rupturing to expose the endoprosthesis. The sheath includes a plurality of circumferential perforations (Figure 3 and column 4, lines 22-28). The sheath has a proximal end secured to the proximal end portion of the catheter and a distal end secured to the distal end portion of the catheter (column 2, lines 39-40). The sheath is also disposed completely over the stent (Figure 2).

Claims 2, 19 and 67, see column 4, lines 22-26 for weakened section.

Claims 4, 5, 21, 22, 24, 68 and 69, see column 2, lines 39-40 and 66-67 for stretching and securing sheath.

Claims 8, 9, 25 and 26, see column 2, lines 35-38 for expandable member being an inflatable dilatation balloon and endoprosthesis being a stent.

Claims 13, 30 and 40, see column 4, line 16 for sheath being formed from an elastomeric material.

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Claims 16, 17, 31, 33, 34, 41, 43 and 44, see column 5, line 14 for sheath being formed from polyurethane.

Claim 66, see abstract and Figure 5 for sheath being configured to rupture into portions which retract towards the first and second ends of the stent after rupturing to expose the stent.

Claim 70, see column 4, lines 22-26 for sheath including plurality of perforations which allow the sheath to rupture during expansion of the balloon.

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 11, 28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson in view of applicant's own admission.

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the catheter including an over-the-wire intravascular catheter, as required by claims 11, 28, 37 and 38. Applicant admits that an over-the-wire catheter is old and well known in the art on pages 20-21, lines 26-2 and Figure 8 of the specification. Because this type of catheter is standard in the art, it would have been obvious for the stent delivery system of Hanson to include an over-the-wire catheter. In addition, it appears from Figures 1-5 of Hanson that the catheter could include an over-the-wire intravascular catheter. At the time the invention was made, it would have been an obvious

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matter of design choice to a person of ordinary skill in the art to have the catheter include an over-the-wire intravascular catheter because Applicant has not disclosed that an over-the-wire intravascular catheter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with other catheters because the ability for the sheath to rupture during expansion of the expandable member is not affected by the type of catheter used. Therefore, it would have been an obvious matter of design choice to modify Hanson to obtain the invention as specified in claims 11, 28, 37 and 38.

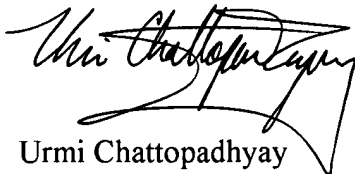
11. Claims 14, 15, 32 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson in view of Makower et al. (USPN 6,302,875 B1 as cited in previous office action).

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the sheath being formed from polyurethane with a shore hardness of 45D or lower or a biodegradable material, as required by claims 14 and 15, 32, 42, respectively. Makower et al. teaches a catheter with a sheath formed from polyurethane having a shore hardness of less than 45D or a biodegradable material, elastin, in order to impart a less rigid and less hard region in the sheath. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Makower et al. to make the sheath of Hanson of a polyurethane having a shore hardness of less than 45D or a biodegradable material in order to impart less rigid and hard characteristics to the sheath so that it will expand with less pressure. See column 7, lines 9-28.

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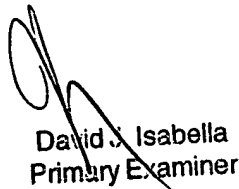
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner

uc

June 20, 2003